PTW FREIBURG

User Manual

CT PHANTOMS
T40016, T40017 and T40027

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General Information

- The product bears the CE-mark "CE" in accordance with the Council Directive 93/42/EEC about Medical Devices and fulfills the essential requirements of Annex 1 of this directive. The product is a class I device without measuring function (MDD).
- The user manual is an integral part of the product. It should always be kept near the product. Observance of the manual is a prerequisite for proper product performance and correct operation.
- Operator safety, specified measuring accuracy and interference-free operation can be guaranteed only if original products and parts are used. Furthermore only the accessories listed in this manual are approved by PTW-Freiburg and may be used in conjunction with the product, or else accessories whose use has been expressly permitted by PTW-Freiburg. Safe operation and proper product performance are not guaranteed if accessories or consumables from other manufacturers are used.
- PTW-Freiburg cannot be held liable for damages resulting from the use of accessories, consumables from other manufacturers or when the user ignores the instructions and information given in this manual.
- The warranty period is 1 (one) year and begins on the day of delivery. It is unaffected by repairs covered by the warranty regulations.
- PTW- Freiburg considers itself responsible for safety, reliability and performance of the product only, if assembly, extension, readjustment, modification or repair is carried out by PTW-Freiburg or by persons authorized by PTW-Freiburg, and if the product is used in compliance with the technical documentation.
- This manual is in conformity with the product specifications and all applicable safety standards valid at printing date. All rights are reserved for devices, circuits, techniques, software and names referred to in the manual.
- No part of the technical documentation may be reproduced without written permission from PTW-Freiburg.
- PTW-Freiburg works in strict accordance with a quality management system which is continuously updated according to national and international standards.

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1 Intended Use

The CT phantoms are PMMA cylinders representing the head or the body to be CT scanned:

- T40016 is a CT head measuring phantom
- T40017 is a CT body measuring phantom
- T40027 is a CT head and body measuring phantom, consisting of a smaller and a larger cylinder. The smaller cylinder is used as a head measuring phantom. In order to get a body measuring phantom the smaller cylinder has to be inserted into the larger one.

CT phantoms are used to determine the Computed Tomography Dose Index (CTDI) in acceptance and constancy tests according to the standards IEC 61223-2-6, IEC 60601-2-44 and FDA §1020.33.

For constancy checks the CTDI must be measured at least after a period of six months or after major maintenance and service activities. The CTDI must comply with the reference value within a tolerance of ± 20 %.

The user manual describes the use of the test object in acceptance and constancy tests of CT equipment based on the standard IEC 61223-2-6.

NOTE

This manual only describes the use of the CT phantoms. For detailed information about acceptance and constancy tests of CT systems please refer to the standard IEC 61223-2-6, IEC 60601-2-44 and FDA §1020.33.

2 For your Safety

The following safety statements are divided into **DANGER, WARNING, CAUTION** and **NOTE**.

Definitions

DANGER

Indicates an imminent hazard. If not avoided, the hazard **will** result in death or serious injury.

WARNING

Indicates a hazard. If not avoided, the hazard **can** result death or serious injury.

CAUTION

Indicates a potential hazard. If not avoided, the hazard could result in minor injury or product / property damage.

NOTE

Provides useful information to assure that you get the most from your equipment.

Safety Information

WARNING

Shock Hazard – Strictly observe the following warnings. Failure to do so may endanger the lives of the patient, the user and other persons involved.

- Before using the product, the operator must ascertain that it is in correct working order and operating condition.
- Liquids must not enter the device. If liquids have entered the device, it must be thoroughly inspected before being used again.

Exclusion of operation in the patient environment: Neither the product nor any peripheral device may be operated within the patient environment (see Figure 1).

Exclusion of operation as device with patient contact: The device is not for use in direct contact with the patient. Neither the device nor any peripheral device may have contact to the patient.

Devices may be connected to other devices or to parts of systems only if it has been ascertained that this connection does not impair the safety of the patient, the operator or the environment.

WARNING

Suffocation Hazard – Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packaging material out of children's reach***.***

Patient Hazard – The product is a medical electrical device and must only be handled by persons who are trained in the use of such equipment and are capable of applying it properly. The operator must be trained in the use of the device.

NOTE

Please observe the user manuals of all connected devices!

NOTE

This symbol stands for:
Please observe the manual !

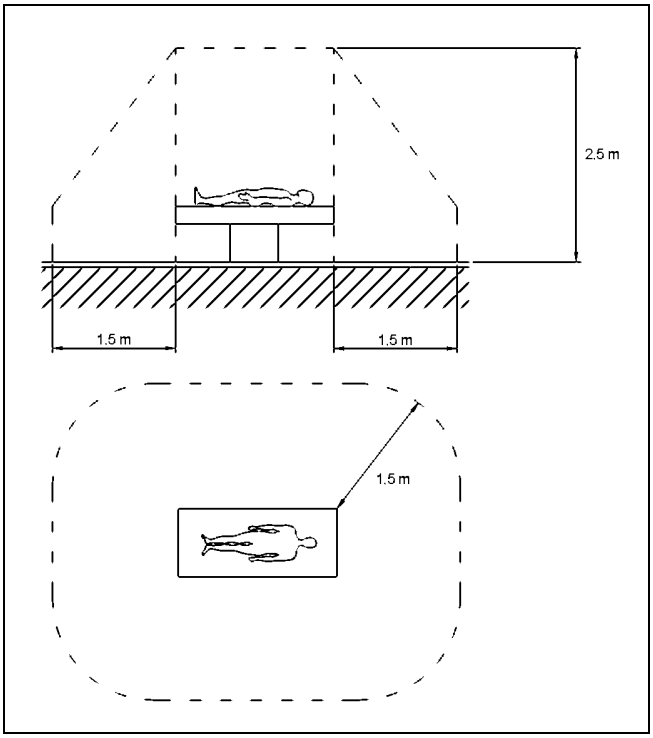

Figure 1: Definition of patient environment

3 Components of the Measuring System

Phantom:

- head (T40017) and/or body measuring phantom (T40016)
  4 acrylic dummy plugs
  support, screw, rubber disk
- head and body measuring phantom (T40027)
  8 acrylic dummy plugs
  support, screw, rubber disk

Measuring equipment:

- dosemeter DIADOS, DIADOS E UNIDOS or UNIDOS E
- CT chamber
- for DIADOS and DIADOS E: CT adapter for chamber HV
- connection cables

CAUTION

Pay attention to use the correct connecting system at chamber and measuring device.

UNIDOS or UNIDOS E: BNT, TNC or PTW-M connector

DIADOS or DIADOS E: M connector

Description of the phantoms:

The phantoms provide holes to insert a chamber or an acrylic dummy plug for the measurements:

- head (T40017) and body measuring phantom (T40016) each with 4 holes off-center and one hole in the center
- both cylinders of the head and body measuring phantom (T40027) each with 4 holes off-center and the smaller cylinder one hole in the center

Etched crosshairs on the phantom allow exact alignment. A support keeps the phantom in its position on the CT couch.

Figure 1: CT chamber, CT body measuring phantom T40016 and CT head measuring phantom T40016

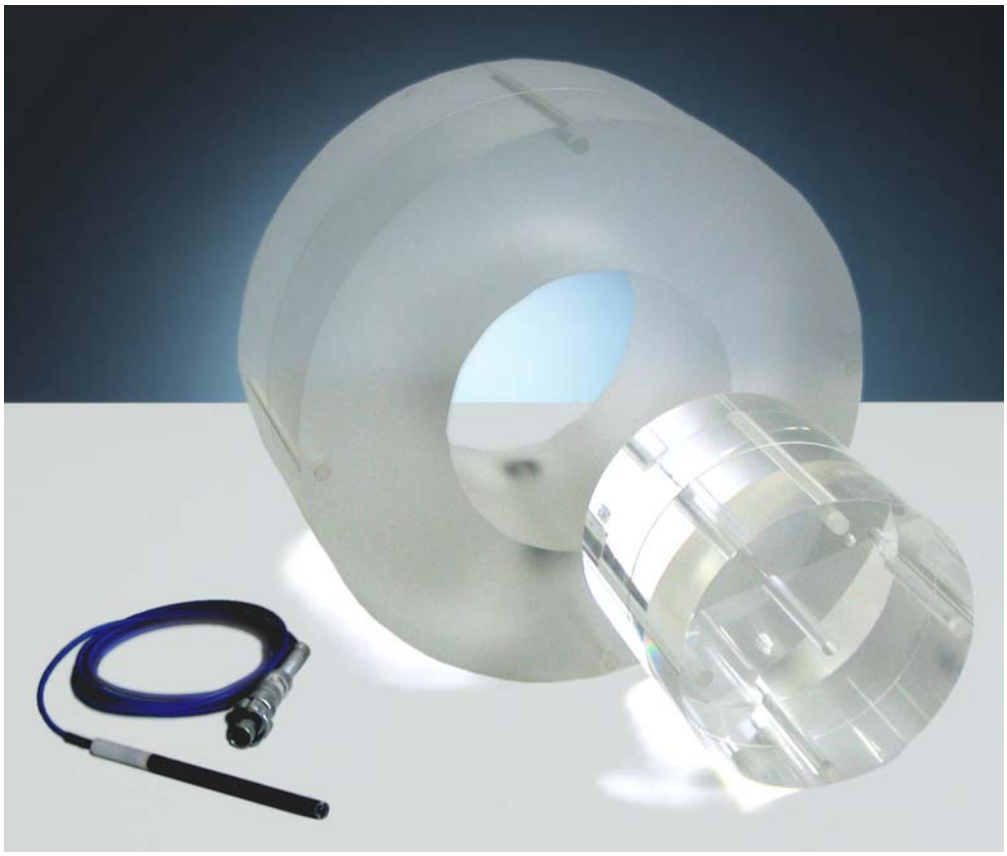

Figure 2: CT chamber and CT body and head measuring phantom T40027

4 Measurement

4.1 General

The phantoms are distinguished only by the diameter, body measuring phantom 32 cm Ø (with phantom T40027 the smaller cylinder inserted into the larger one) and head measuring phantom 16 cm Ø.

The assembly of the measuring system and the measurement is the same for all phantoms.

4.2 Preparing for a Measurement

(1) Prepare the protocol. Enter necessary data according to the standard.

(2) Set up the measuring device and the chamber according to their user manuals.

(3) Put the phantom on the table top of the patient treatment couch.

(4) Set up the phantom. Use the support, screw and rubber disk of the phantom. Turn the phantom so that one of the outer holes is in the twelve o'clock position. Tighten the screw.

NOTE

If you do not use the rubber disk and the screw is not tighten strong enough the support can displace because of the high weight.

(5) Insert the chamber into the hole in twelve o'clock position or in the position with maximum exposition. Insert the acrylic dummy plugs into the holes not used.

NOTE

For CT equipment performing scans with less or more than 360°: the selected position has to represent the area of maximum patient dose.

(6) Align the phantom with respect to the CT plane and rotational axis using the crosshairs of the phantom.

4.3 Performing a Measurement

(7) Set up the CT for the scan.

(8) Start the measurement of DLP (dose-length-product) at the measuring device. Perform the scan.

(9) Stop the measurement. Read the values from the measuring device and enter the data into the protocol.

(10) Change the chamber position. Insert the chamber into the center hole and the acrylic dummy plugs into the not used holes.

CAUTION

Change the chamber and dummy plugs carefully. If the phantom is moved the alignment has to be repeated.

(11) Set up the CT for the scan.

(12) Start the measurement of DLP at the measuring device. Perform the scan.

(13) Stop the measurement. Read the values from the measuring device and enter the data into the protocol.

For the determination of the weighted Computed Tomography Dose Index ($CTDI_W$) the DLP has to be measured corresponding step (1) to (13) in all four outer holes and the center hole.

5 Evaluating the Results

The evaluation and interpretation of the results are in the responsibility of the user.

CTDI

Determine the CTDI (Computed Tomography Dose Index) from the measured DLP.

Compare the determined CTDI with the baseline value. Compare the deviation with the allowed deviation from the standard. If the deviation is too high take steps to eliminate the errors.

$CTDI_W$

Determine the $CTDI_W$ (Computed Tomography Dose Index) from the measured DLP values.

Compare the determined $CTDI_W$ with the baseline value. Compare the deviation with the allowed deviation from the standard. If the deviation is too high take steps to eliminate the errors.

6 Cleaning, Preventive Maintenance and Disposal

6.1 Cleaning and Disinfection

Wipe off the phantom only with a moist cloth.

Do not immerse the phantom into water.

Use only the following disinfectants with the given concentrations:

- 2% solution of KORSOLIN
- 1% aqueous solution SOKRENA
- 5 % solution Sagrotan
- 5 % solution Gigasept

6.2 Preventive Maintenance

Check the phantom before using for mechanical damages.

6.3 Disposal of the Product

At the end of the life time of the phantom you have to dispose the components in accordance with legal local requirements.

Ensure a careful separation of the materials.

The phantom does not contain any hazardous goods.

The cost for an eventual return at the end of the product life time is to be borne by the customer.

7 Technical Specifications

Only values for which tolerances or limits are specified are guaranteed. Values for which no tolerances are specified are for information only.

Device designation	CT head measuring phantom CT body measuring phantom CT head and body measuring phantom	
Manufacturer	PTW-Freiburg	
Intended Use	Determination of the Computed Tomography Dose Index (CTDI) in acceptance and constancy tests	
Dimensions and Weight	**Dimensions**	**Weight**
CT head measuring phantom	Cylinder with 16 cm Ø and 15 cm length	3.6 kg
CT body measuring phantom	Cylinder with 32 cm Ø and 15 cm length	14.4 kg
CT head and body measuring phantom	Cylinder with 16 cm Ø and 15 cm length and Cylinder with 32 cm Ø and 15 cm length The smaller cylinder can be inserted into the larger one.	14.4 kg

8 Order Information

CT body measuring phantom 15 cm long acrylic cylinder, 32 cm in diameter. Features hole in the center and four holes off-center for accommodation of CT ionization chamber 30009. Includes 4 blind plugs. For dose measurements in accordance with IEC 61223-2-6	T40016
CT body phantom carrying case Carrying case for CT body phantom T40016	T40016.1.010
Mounting bracket for CT-Phantoms for fixation of the CT head or body measuring phantom to GEMS CT installations	T40016.1.020
CT head measuring phantom 15 cm long acrylic cylinder, 16 cm in diameter. Features hole in the center and four holes off-center for accommodation of CT ionization chamber 30009. Includes 4 blind plugs. For dose measurements in accordance with IEC 61223-2-6	T40017
CT head phantom carrying case Carrying case for CT head phantom T40017, DIADOS dosemeter, CT chamber and accessories	T40017.1.010
CT head & body phantom two 15 cm long acrylic cylinders, 16 and 32 cm in diameter. The big cylinder can accommodate the small one. Both cylinders feature four holes off-center and one central hole for CT chamber 30009. For dose measurements in accordance with IEC 61223-2-6	T40027
CT phantom and DIADOS E carrying case carrying case for CT phantom T40027, DIADOS E dosemeter, CT chamber and accessories	T40027.1.050
CT ion chamber 4.73 cc ion chamber for dose length product measurements in CT. Length of measuring volume 150mm, cable length 2.5 m, connecting system M	TM77336
CT ion chamber 3.14 cc ion chamber for dose length product measurements in CT. Length of measuring volume 100mm, cable length 2.5 m, connecting system M	TM30009
DIADOS diagnostic dosemeter measures dose, dose rate, dose per pulse, and exposure time with semi-conductor detectors. Electrometer mode, RS232 interface and rechargeable battery included. For 115/230V, 50-60Hz	T11003
DIADOS E diagnostic dosemeter complies with IEC 61674. Measures dose, dose rate, dose per pulse, and exposure time with semi-conductor detectors. Electrometer mode, RS232 interface and rechargeable battery included. Requires power supply L991041	T11035
DIADOS CT adapter, connecting system M for connection of a CT chamber type TM30009 or TM77336 to the DIADOS. Supplies the CT chamber with a voltage of 100V	T16018
UNIDOS Universal Dosemeter, System M secondary standard reference class dosemeter for dose and dose rate measurements in radiotherapy, diagnostic radiology, mammography and health physics. Includes RS232, rechargeable batteries and mains cord for 115/230V, 50-60Hz	T10001
UNIDOS E therapy and diagnostic dosemeter, for dose and dose rate measurements. Connecting system M. Includes RS232, rechargeable batteries and mains cord for 115/230V, 50-60Hz	T10008

Literature

[1] The Council of the European Communities, Council Directive 93/42/EEC of June 1993 concerning medical devices (Medical Device Directive - MDD)

[2] The Council of the European Communities, Council Directive 97/43/EURATOM on health protection of individuals against the danger of ionizing radiation in relation to medical exposure

[3] IEC 61223-2-6
Evaluation and routine testing in medical imaging departments
Part 2-6: Constancy tests, X-ray equipment for computed tomography

[4] IEC 60601-2-44
Medical electrical equipment
Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

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